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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,294	06/19/2001	Lonnie O'Neal Ingram	BCI-026	2663

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

8

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/885,294

Applicant(s)

INGRAM ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,14-17,34,35 and 43-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-13,18-33 and 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The application should be reviewed for errors.

Applicant's election with traverse of Group I, which encompasses claims 1, 3-4, 6-13, 18-33, and 36-42 to the extent that they are directed to the production of alcohol in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the pending claims represent an intricate web of knowledge, continuity of effort and consequences of a single invention and that there is no serious burden in examining all of the claims.

However this is not found persuasive because the composition as claimed has multiple distinct uses and the methods as claimed require a different medium having different ingredients, and of these methods each has a different purpose and scope and the references which would be applied to a method of making alcohol would not necessarily anticipate or render obvious the other method of increasing cell growth.

Moreover, as to the question of burden of search, the alleged "substantial overlap" in subject matter and classification of subject matter in class 435 is not persuasive of lack of serious burden. Classification is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 1, 3-4, 6-13, 18-33, and 36-42 will be examined only to the extent that they pertain to a method of increasing the production of alcohol.

Claims 2, 5, 14-17, 34-35 and 43-55 are withdrawn from consideration as directed to a non-elected invention.

The disclosure is objected to because of the following informalities: The ATCC number is missing with respect to strain LY01..

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4, 6-10, 13, 22-27, 30-36, 38-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,130,076.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 is generic to all that is recited in the claims 1 of U.S. Patent No. 6,130,076.

That is, claim 1 of U.S. Patent No. 6,130,076 falls entirely within the scope of claim 1 or, in other words, claim 1 is anticipated by claim 1 of U.S. Patent No. 6,130,076. Specifically, the nutrient medium containing hydrolyzed soy or autolyzed yeast of the patent No. 6,130,076 contains at least amino acids as compounds of claim 1.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel strains of bacteria. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 14 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

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7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Also, the ATCC deposit number is missing with respect to strain LY01..

Claims 1, 3-4, 6-13, 18-33, and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim 1 is vague and indefinite in that the extent of "increasing" cannot be readily ascertained. Is it 0.0001%, 0.001%, 1%, 10%, 50%?

Claims 3, 6-9, 18-33, and 38-42 are incomplete as depending on a non-elected claim.

Claim 9 is incomplete in the omission of the ATCC number.

Claim 1 is confusing in the recitation of "exposing" as a process step, since it is unclear whether there is "contact" with the compound. The extent of "exposure" is not clearly delineated. Is it a nanosecond, a few seconds, a minute, an hour, etc.?

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-4, 6-13, 18-33, and 36-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Ingram '076.

The claims are directed to a process of producing increased alcohol production, including ethanol, wherein exposure to at least a certain compound is provided.

Ingram discloses a process of producing increased alcohol production, including ethanol, wherein exposure to yeast autolyzate (yeast extract) or soy hydrolyzate is provided. Yeast extract and soy hydrolyzate are complex mixtures derived from yeast and plant biomass respectively, which comprise compounds as claimed, including various amino acids and citric acid intermediates. See, e.g., Example 2, Table 1 and instant claim 10.. Process parameters are disclosed at col. 5-6.

Claims 1, 3-4, 6-9, 22-27, 29-33, and 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi *et al.*.

The claims are directed to a process of producing increased alcohol production, including ethanol, wherein exposure to at least a certain compound is provided.

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Takahashi *et al.* disclose a process of producing increased alcohol production, including ethanol, wherein exposure to acetic acid is provided, which is a compound as claimed (See, e.g., Table I, page 198). See Materials and Methods for process parameters. Note that the results at pH 6.5 are shown at page 201.

Claims 1,3,4,5,13,22-24,27,29-33,36-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Albers *et al.*

The claims are directed to a process of producing increased alcohol production, including ethanol, wherein exposure to at least a certain compound is provided.

Albers *et al.* disclose a process of producing increased alcohol production, including ethanol, wherein exposure to glutamic acid or a mixture of amino acids is provided, one or more of which are at least a compound as claimed. See, e.g., Table 3, page 3192. See Materials and Methods for process parameters.

Claims 1, 3, 4, 22-25, 27, 29-33, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Quratulain *et al.*

The claims are directed to a process of producing increased alcohol production, including ethanol, wherein exposure to at least a certain compound is provided.

Quratulain *et al.* disclose a process of producing increased alcohol production, including ethanol and butanol, wherein exposure to an aromatic group amino acid provides for increase in butanol production and exposure to an aromatic amino acid and histidine provides for increased butanol and ethanol production, which are compounds as claim designated (See, e.g., Table 1, page 330). See Materials and Methods for process parameters.

Claims 1, 3-4, 6-13, 18-33, and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi *et al.* taken with Ingram.

The claims are directed to a process of producing increased alcohol production, including ethanol, wherein exposure to at least a certain compound is provided.

Takahashi *et al.* disclose a process of producing increased alcohol production, including ethanol, wherein exposure to a acetic acid is provided, which is a compound as claimed (See, e.g., Table I, page 198). See Materials and Methods for process parameters. Note that the results at pH 6.5 are shown at page 201. The reference differs from the claimed invention in that the only compound disclosed as suitable for addition is acetic acid. However, Ingram discloses

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that complex mixtures of at least amino acids are suitable for the improvement in the production of alcohols, such as yeast extract and soy hydrolyzate.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in obtaining improved yields of alcohols when using additives to the culture medium such as acetic acid and at least amino acids as contained in complex mixtures of nutrients.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of producing ethanol with recombinant bacteria of Takahashi *et al.* by substituting various organic acids including amino acids for acetic acid, as suggested by the teachings of Ingram, for the expected benefit of maximizing the yields of the useful fuels and solvents, such as ethanol in microbial fermentation.


Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651